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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/049,847 | 03/27/1998 | SYLVIE BAY | 102.166A | 6142 |

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EXAMINER

WESSENDORF, TERESA D

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/049,847

Applicant(s)

BAY ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-32,35,38-40,42-44,46 and 47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-32,35,38-40,42-44,46 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☒ Other: *CRF error report*.

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of B4-T4-M and B as tumor antigen, T as 103-115 protein of poliovirus type I in Paper No. 26 is acknowledged. The traversal is on the ground(s) that the present application is a RCE and the original application received three office actions on the merits with the present claims and it is deemed that there is but a single invention present. The restriction requirement is withdrawn since the elected species have been examined in the previous Office actions.

Status of Claims

[Claims 1-14 and 17-25 have been cancelled in the Amendment of 9/28/00. Claims 15-16, 26-28 have been cancelled in the amendment of 2/2/00. (Summarizing the status of the original claims)].

Claims 29-47 have been added in the Amendment of 9/28/00.

Claims 33, 34, 36-37, 41, 45 have been cancelled in the Amendment of 5/3/01.

Claims 29-32, 35, 38-40, 42-44, 46-47 are under consideration. (The REMARKS of 12/6/01 omitted claims 38 and 39 as under examination.)

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Specification

The disclosure is objected to because of the following informalities:

There is no Sequence Identifier No. for the sequence KLFAVWKITYKDT at page 15, line 24 and page 28, line 22. Applicants have not assigned a Sequence ID. No. for this sequence and 3-letter codes instead of the single letter code, as required under 37 CFR 1.825. The objection to the disclosure is maintained. Applicants are requested to check for other sequences in the specification that have not been assigned an ID No.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-32, 35, 38-40, 42-44, 46-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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A. The as-filed specification does not provide support for the structures as recited in the presently amended claims. The figures that contain the newly presented claims do not recite for the middle Lys residue as being of 9-13 residues as defined by the variables n and m.

B. The specification fails to provide a description of the structure wherein the Lys contains more than 3 residues as given in the Figures. There is no description as, for example, how the more than 3 Lys residues are linked together to form the Lys bridge.

Response to Arguments

Applicants' arguments filed 5/3/01 have been fully considered but they are not persuasive.

A). Applicants argue that page 7, lines 19-22 recites that a conjugate encompassed by the invention "comprises at least 3 lysine and up to 15 lysine residues covalently linked to one another." A review of page 7 of the instant specification does not reveal the argued lysine (lys) residues as comprising at least 3 lysines and up to 15 lysines. Claim 29 recites n and m in the range of 1-9(or 13). Applicants' arguments and the alleged support in the specification are inconsistent with claim 21.

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B. The response above applies herein since applicants present the same argument above in combination with Figure 1.

The following rejections under 112, first paragraph are applied to the newly amended claims:

A. The specification fails to provide a written description for a vaccine or immunogenic composition effective against tumors using the conjugate. A vaccine indicates a protective effect against all or any kinds of tumors. The complex nature of tumors, let alone its cure, to date remains still elusive. For some tumors, the etiologic agent that causes said tumor remains undefined. To date agents believed to have therapeutic effect against tumors are only candidates or promising leads for said therapy. Example (3) in the specification, page 27 describes protection induce by the conjugate against murine adenocarcinoma in mice. There is no indication whether similar results can be obtained for the claimed humans, or that the specific tumor, adenocarcinoma, using any of the conjugate or combinations would be applicable for all types of tumors to all humans. [Note applicants' statement at page 9 of the instant REMARKS relying on the Dalglish reference as to the "numerous problems which are encountered when an anti-tumor immune response is desired"].

Also, the specification fails to provide an adequate description of the different derivatives of the carbohydrate

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tumor antigen. The specification provides a general description of the derivative. Other than the general description, the exemplification is nil or directed to the single sugar moiety galactosyl-N-acetyl serine. Even for this single sugar moiety, it does not describe the other different carbohydrates included in the scope of the claimed different forms of the B conjugate coupled to the dendrimer or method of said coupling.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-32, 35, 38-40, 42-44, 46-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claim 29 is unclear as to the attachment of the T and B to the Lys residue. Is it at the alpha or epsilon amino group?

B). Claim 31 recitation of "at least 4 T cell epitopes" is confusing since the base claim shows not more than four T cell epitopes for B2-T2-M.

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Response to Arguments

Applicants consolidated the rejections above into a single argument. It is argued that claim 29 has been amended with the limitation of "comprising a dendrimeric polylys carrier enabling multiple epitopes to be covalently attached thereto..." from claim 33, to obviate the rejection under paragraph A above. Firstly, claim 33 does not contain this limitation. Secondly, the added limitations provide for confusion. (See the new grounds of rejection, below). Therefore, the rejection of claim 29 under paragraph A is maintained.

The rejections under paragraph B is maintained since applicants have not presented any response.

The following rejections are applied to the newly amended claims:

1. In claim 29, "enabling multiple epitopes" connotes uncertainty as to the conjugation or number of a multiple epitopes. The metes and bounds of the recited: "multiple", "derivative", "several identical or "different" B epitopes or T epitopes are not clearly set forth in the claims or specification. It is not clear whether the several or multiple epitopes correspond exclusively to those present in the formula or more. If so, then these terms are redundant. "B denotes a structurally defined carbohydrate moiety" is indefinite since

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there is no structure defined in the claims for the carbohydrate tumor antigen. "Sailoside" is misspelled.

2. In claim 35" the carbohydrate is grafted" is unclear as to how grafting of said carbohydrate is achieved.

3. Claim 38 "T* antigen" is unclear as to its constituent especially in the absence of positive support in the specification. It is suggested that the full name of the abbreviated "Tn" be provided.

4. Claim 40 is indefinite as to the other components comprised in the vaccine. This is a duplicate of claim 39 except that it functions as a vaccine. Likewise, claims 42-43 are duplicates of the composition. Recitation of the function of the composition does not make a composition different. "Capable" denotes uncertainty. "More" efficient (claim 43), "increasing" the survival are relative terms, the basis or standard by which said terms are measured are unclear, especially for all kinds of tumors.

5. Claim 46 is indefinite as to the induction of an immune response to only B cell i.e., how the conjugate is able to block the response to T-cell when the conjugate contains both T and B cells, especially as applied to humans.

6. Claim 47 is a duplicate of claim 44 since the method steps and components administer i.e., the conjugate are the same.

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Double Patenting

Claims 29-32, 35, 38-40, 42-44, 46-47 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-14, 24-29 and 33-36 of copending Application No. 09/405,986 (the '986 application) for reasons of record.

Response to Arguments

Applicants argue that due to the 15-way restriction requirement in the copending '986 application, claims 17-22 were elected which are drawn to a linear carbohydrate conjugate and is not in conflict with the claims of the present application. But the linear carbohydrate is the same as the instant linear carbohydrate conjugate claim. The claims in the '986 application have been merely withdrawn from further consideration but are still pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29-32, 38-40, 42-44, 46-47 are rejected under 35 U.S.C. 103(a) as being obvious over Chong et al (5,679,352) for reasons stated in the previous Office actions or Chong in combination with Jondal (5,807,559).

Applicants argue that Chong discloses MAG constructs wherein a carbohydrate moiety is a bacterial antigen derived from Hemophilus influenzae. The production of an immune response against the bacterial antigen cannot predict that any MAG construct would also be efficient for stimulating an immune response against a tumor antigen. Applicants rely on the newly submitted Chamberlain, Pardoll and Dalglish references as showing that one skilled in the art could not transposed the area to anti-tumor vaccines. Chong discloses at col. 17, lines 27-32 that the synthetic glycoconjugate may be used to produce vaccines eliciting antibodies against proteins or oligosaccharide. Such vaccines may be used to induce immunity toward tumor cells, or to produce antitumor antibodies. Accordingly, the suggested teachings of Chong would lead one skilled in the art to the claimed anti-tumor vaccine. The disclosure of Jondal, col. 10, Table 1 supports the findings of Chong. Jondal discloses a conjugate of protein and tumor or bacterial antigen effective as anti-tumor or anti-bacterial antigen i.e., depending upon the vaccine or immunity one desires i.e., whether an antitumor or antibacterial vaccine. The important aspect of the conjugation of protein-polysaccharide

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conjugates is the desire to elicit both T and B cells responses. As applicants recognized, Chong et al at lines 38-43, col. 3, is concerned with the enhancement of carbohydrate immunogenicity by the use of MAP type constructions containing Hib determinant as carrier molecules for the carbohydrate moiety, more precisely, the PRP carbohydrate moiety. Applicants further recognized, col. 5, lines 29-39 that Chong encompasses the use of peptides consisting of immunodominant epitope for T-cells as PRP carriers or as autologous or heterologous B-cell epitope carriers.

The three references rely upon does not disclose any conjugate and nothing more than a general teaching of a tumor vaccine.

Claims 30 and 38 are obvious over the teaching of Jondal at Table 1, col. 10.

Claims 39-40, 42-44 and 46-47 are obvious over the disclosure of Jondal at col. 11, lines 45-45; col. 5, lines 45-55.

Claims 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chong et or Chong in view of Jondal further in view of Tam [5,229,490(I) or 5,580,563(II)) for reasons of record.

Since applicants have not responded to the rejection over Tam, then it is believed that applicants are acquiescing therewith.

No claims are allowed.

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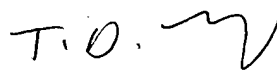
REASSIGNMENT OF LOCATION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit **1639**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
January 25, 2003